OGB Poly Care 2
Incubator
Service Manual

THIS MANUAL HAS BEEN REALIZED
RESPECTING THE ENFORCED NORMS

Index

1 PRESENTATION 4

2 "EC" CERTIFICATE 5

3 CALIBRATION CHECK 6

3.1 TEMPERATURE PROBES CALIBRATION 6

4. ELECTRICAL INTERCONNECTION DIAGRAM 8

5. SPARE PART 10

5.1 INCUBATOR POLY CARE 2 10
5.2 LOCKED POWER CONTROL PANEL 12
5.3 ASSEMBLED BODY INCUBATOR 14
5.4 ASSEMBLED WATER BOX 16
5.5 ASSEMBLED CONTROL PANEL 18
5.6 ASSEMBLED HOOD 20
5.7 ASSEMBLED BASAMENT 21
5.8 CONTROL PANEL LOCKED KEYBOARD 23
5.9 ASSEMBLED WOOD DOOR 25

6. MAINTENANCE SERVICE 26

7. PROGRAMMED AND PREVENTIVE MAINTENANCE 27

8. FINAL CHECK 28

9. TECHNICAL DATA 29

10. OGB POLY CARE 2 COMPLIES WITH THE FOLLOWING STANDARDS: 30

1 PRESENTATION

Dear customer,
we would like to thank you for choosing our Incubator "OGB Polycare 2". Ginevri's quality, long experience, safety and easy maintenance will prove to be the best reward for your continuous interest in our products line.

Giorgio Ginevri

GINEVRI s.r.l. – Registered office
Via Giacomo Boni - 00162 Roma

Before using the device, all personnel, who will be working with the unit, should read and thoroughly understand this manual.

This manual provides instructions for calibration and operator maintenance. Ginevri cannot be responsible for the performance of the Incubator "OGB Polycare 2" if the user does not operate the unit in accordance with the instructions, fails to follow the maintenance recommendations in this manual, or effect any repairs with unauthorized components.

Calibration and repair should be performed only by qualified service personnel. Technical information is available through your local distributor.

If there is anything you do not understand, please contact your Ginevri's representative for further information.

GINEVRI srl - Servizio Assistenza Clienti

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Tel. ++39 06 93459331 Fax ++39 06 93459393
E-mail: export@ginevri.com
www.ginevri.com

This manual refers to the enclosed equipment:

Incubator OGB Polycare 2

S/N _____

2 “EC” CERTIFICATE

CERTIFICATO CE

Certificato n. 747/MDD

Allegato

Incubatrici neonatali da reparto
Modd. OGB Poly Care 1; OGB Poly Care 2; OGB Poly Care 3; OGB Poly Care 4; OGB polytrend.
Marca Ginevri

Incubatrici neonatali da trasporto
Modd. Baby Shuttle Normal Care; Baby Shuttle Special Care; Baby Shuttle Intensive Care.
Marca Ginevri

Isole neonatali
Modd. IW409; IW509; IW909.
Marca Ginevri

Serie: IW509 PLUS.
Marca Ginevri

Serie: Isola Neonatale Modd. ALHENA PLUS ELEVABILE; ALHENA PLUS FISSA; ALHENA ELEVABILE; ALHENA FISSA.
Marca Ginevri

Materassini riscaldanti per uso pediatrico
Mod. Acquatherm.
Marca Ginevri

Analizzatori d'ossigeno
Mod. LCD 1000.
Marca Ginevri

Tende per ossigeno terapia
Modd. Oxytent 1000; Oxytent 2000.
Marca Ginevri

Apparecchi per fototerapia per iperbilirubinemia neonatale
Modd. IP; IPR; RPR; RPS; D; GN; Bililight.
Marca Ginevri

Riscaldatori ausiliari neonatali
Mod. Hot Spot.
Marca Ginevri

Compressori aria per incubatrici da trasporto

Emesso il: 2004-04-21
Data di Aggiornamento: 2009-11-09
Sostituisce: 2009-04-17

IMQ

3 CALIBRATION CHECK

Every three months check the Temperature, probes correct operation.
To check the probes reading use the optional Ginevri **Reference Simulator P/N 10487A60.**
To check the reading of the probes perform the following steps:

Temperature probes

a) Switch off the equipment and disconnect it from the mains
b) Disconnect from the control panel the probe assembly connector and replace it with the **Reference Simulator**
c) Connect the equipment to the mains and switch on
d) Select on the **Reference Simulator**: PROBES on AIR 1
TEMP °C on 25°C
SELECT on MUTE
The AIR LED display should show the selected reading with a ±0.2°C tolerance for temperatures lower then 30°C and with a ±0.1°C tolerance for temperatures higher than 30°C.
Repeat this step for all the temperature settings

e) Check the AIR2 and SKIN Temperature probes selecting AIR2 first and then SKIN on the simulator dial and performing the same operations of the preceeding step
f) Select on the **Reference Simulator** : PROBES MAX TEMP
TEMP °C on 39.8°C
SELECT on H.T.
check that the MAX TEMP alarm does not activate.
Select on the **Reference Simulator**: TEMP °C on 40.1°C And check that the MAX TEMP alarm activates.

If the readings of the probes are not correct, within the specified tolerances, the probes should be calibrated.

The calibration is performed by means of the **Reference Simulator** as described in the following chapters.

3.1 TEMPERATURE PROBES CALIBRATION

ATTENTION: Unless specified, the temperature probes calibration is performed on the microprocessor board (PN 7477).

To calibrate the temperature probes perform the following steps:

a) Switch off the equipment
b) Open the control panel to be able to access the boards
c) Disconnect from the control panel the probe assembly connector and replace it with the **Reference Simulator**
d) Connect the equipment to the mains and switch on, if an alarm activates mute it by MUTE push button.

AIR 1 e) Select on the **Reference Simulator**: PROBES on AIR 1

TEMP °C	on 25°C
SELECT 1	on MUTE

f) connect the negative lead of the multimeter to PIN 2 of J5, connect the positive lead of the multimeter to TP1

g) Adjust the trimmer R29 to read on the multimeter 1060 mV ±1

h) Select on the **Reference Simulator**: TEMP °C su 36°C

i) Disconnect the multimeter

j) Adjust the trimmer R 28 to read 36°C ±0.1 on the AIR display of the control panel

k) Check the calibration Selecting on the **Reference Simulator** dial all the settable values, with the exception of 0°C and MAX TEMP, verifying that the set value is displayed on the AIR display (to obtain a correct reading each set temperature value should be kept for at least 10 seconds) the reading should be between the following tolerances

< 30°C	±0.2°C
> 30°C	±0.1°C

AIR 2

l) Select on the **Reference Simulator**: PROBES on AIR 2
TEMP °C on 36°C

m) Adjust the trimmer R31 to read 36°C ±0.1 on the AIR display of the control panel. Follow the instructions of step k) setting the PROBES dial of the reference simulator first on AIR1 And then on AIR2.

SKIN

n) Select on the **Reference Simulator**: PROBES on SKIN
TEMP °C on 36.5°C

o) Adjust the trimmer R30 to read 36.5°C ±0.1 on the SKIN display of the control panel. . Follow the instructions of step k) setting the PROBES dial of the reference simulator first on AIR1, AIR2 And then on SKIN.

MAX TEMP

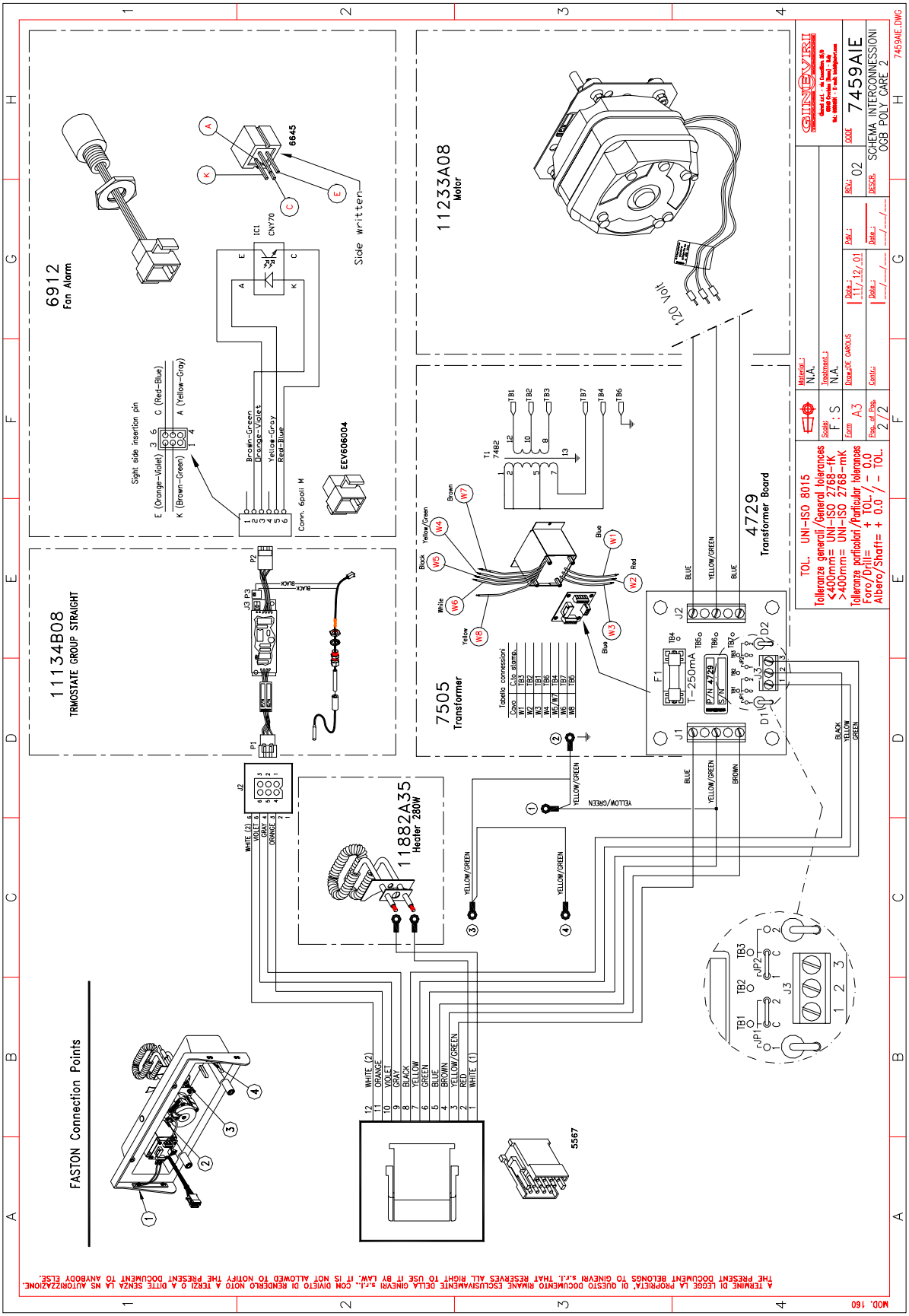
p) Select on the **Reference Simulator**: PROBES on MAX TEMP
TEMP °C on 40°C
SELECT on H.T.

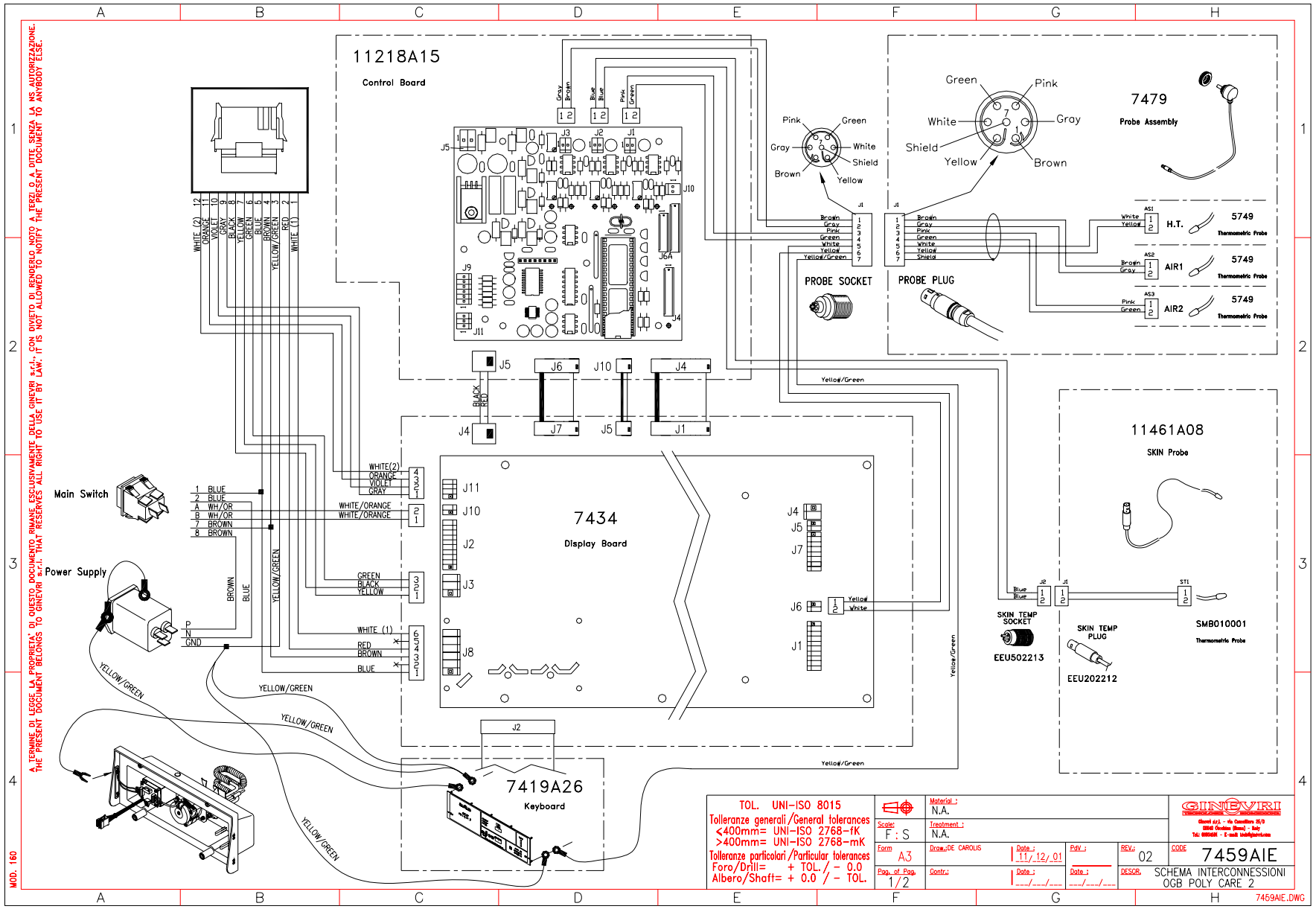
The alarm should be active.

q) Adjust the trimmer PT 101 placed on display board half way between alarm activated and not activated. Adjust the trimmer PT 101 to have the MAX TEMP alarm activated.

r) Select on the Reference Simulator VAR condition and adjust the potentiometer placed in the simulator to have the MAX TEMP alarm activated. Select on the Reference Simulator AIR 1 and verify that it is possible to read on incubator air display a value of 40.0°C ± 0.1°C , if necessary repeat the q) point.

4. ELECTRICAL INTERCONNECTION DIAGRAM





A TERMINE DI LEGGE, LA PROPRIETA' DI QUESTO DOCUMENTO RIMANE ESCLUSIVAMENTE DELLA GINEVRI S.r.l., CON DIVIETO DI RENDERLO NOTO A TERZI O A DITTE SENZA LA NS. AUTORIZZAZIONE.
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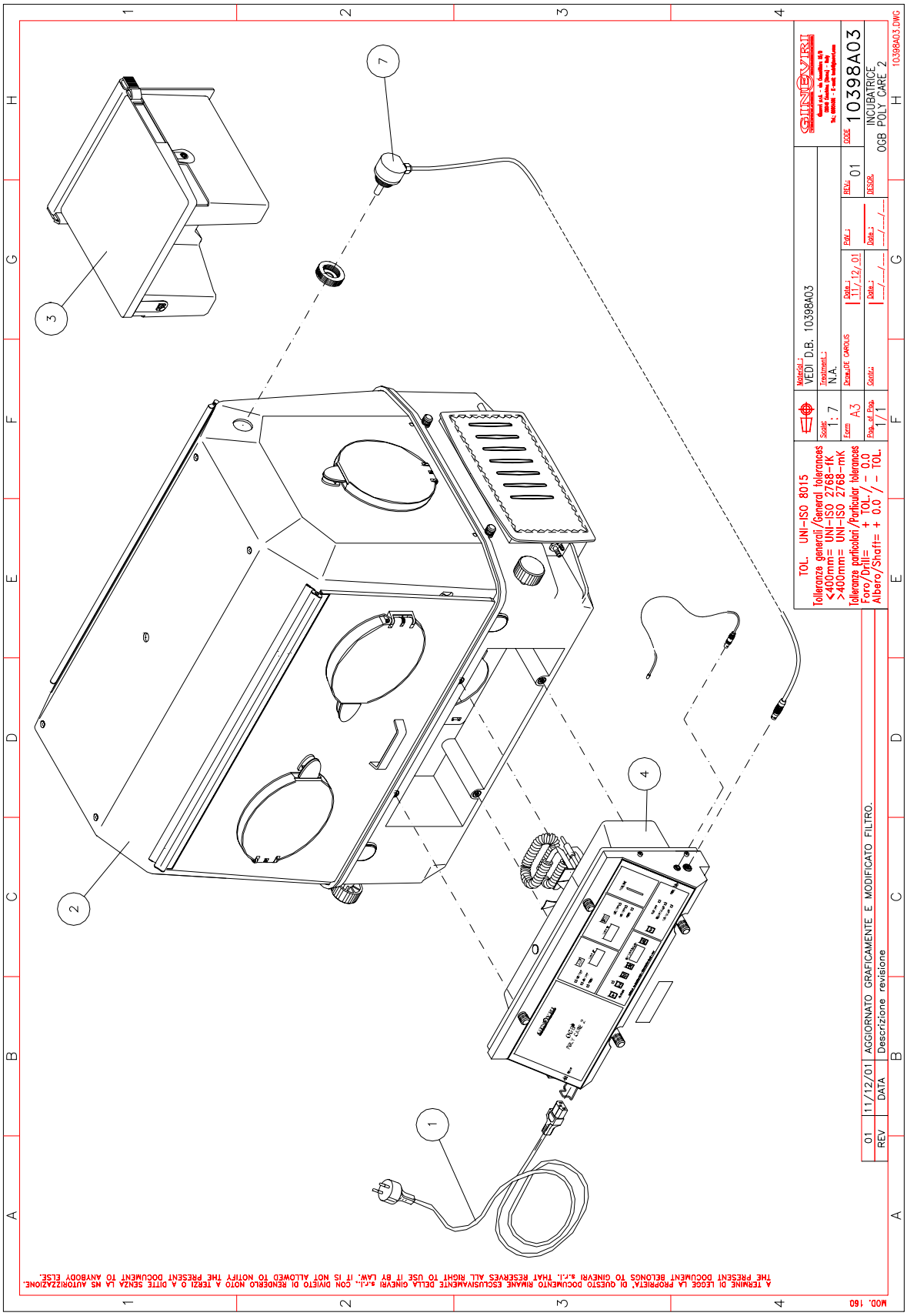
5. SPARE PART

5.1 INCUBATOR POLY CARE 2



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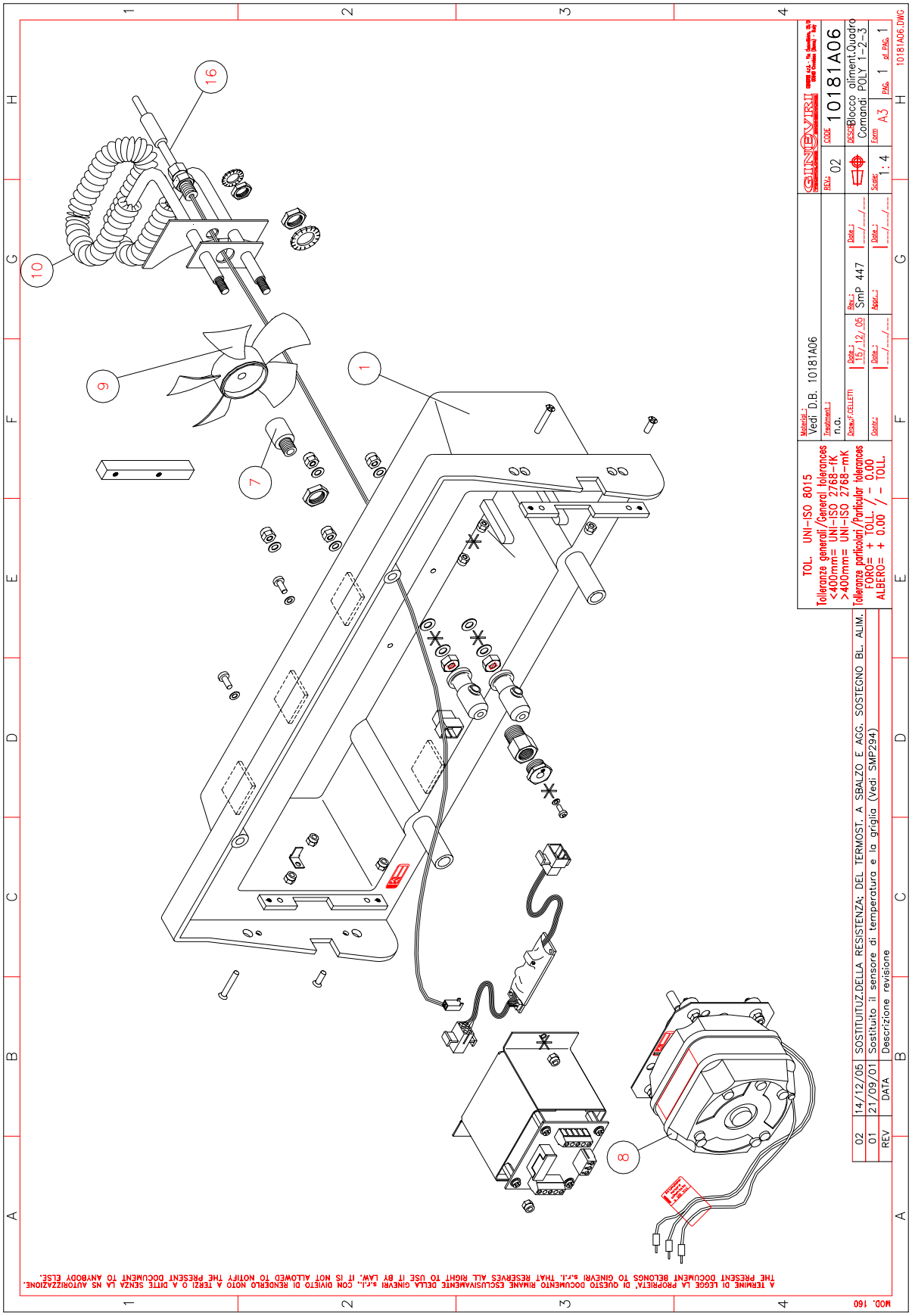
Item.	*Code*	*Description*	*Q.ty*
1	11885A72	POWER CABLE 3 M	NR 1
2	10226A72	ASSEMBLED BODY INCUBATOR	NR 1
3	10239A72	ASSEMBLED WATER BOX	NR 1
4	10376A72	ASSEMBLED CONTROL PANEL	NR 1
7	7479A72	AIR HOLDER PROBES GROUP	NR 1

5.2 LOCKED POWER CONTROL PANEL


16
10
9
1
7
8
GINEVRI
10181A06
Blocco alimentQuadro Comandi POLY 1-2-3
TOL. UNI-ISO 8015
Tolleranze generali/Generel tolerances
<400mm= UNI-ISO 2768-fK
>400mm= UNI-ISO 2768-mK
Tolleranze particolari/Particular tolerances
FORO= + TOLL. / - 0.00
ALBERO= + 0.00 / - TOLL.
02 14/12/06 SOSTITUITUZ.DELLA RESISTENZA; DEL TERMOST. A SBALZO E AGG. SOSTEGNO BL. ALIM.
01 21/09/01 Sostituito il sensore di temperatura e la griglia (Vedi SMP294)
REV DATA Descrizione revisione
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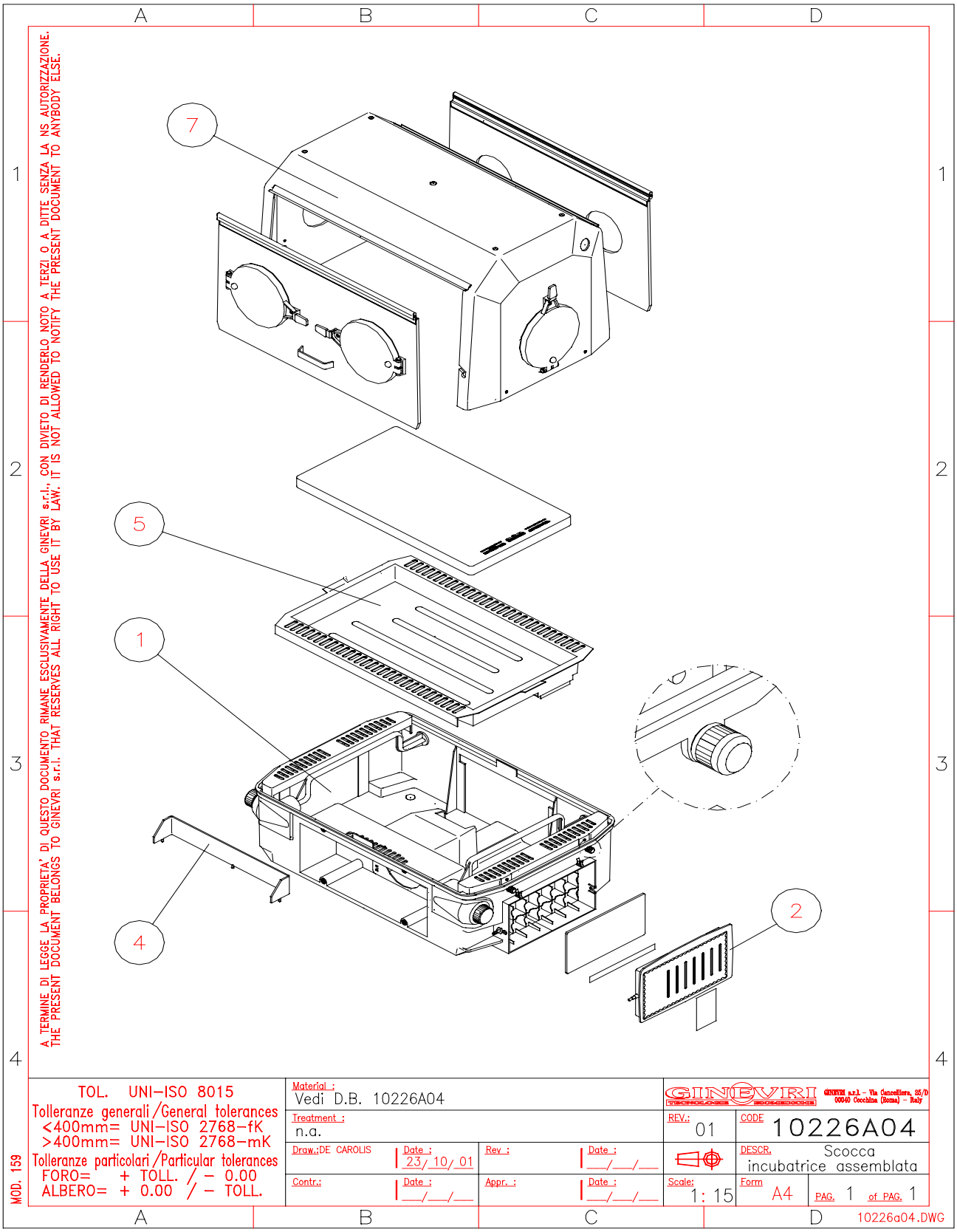
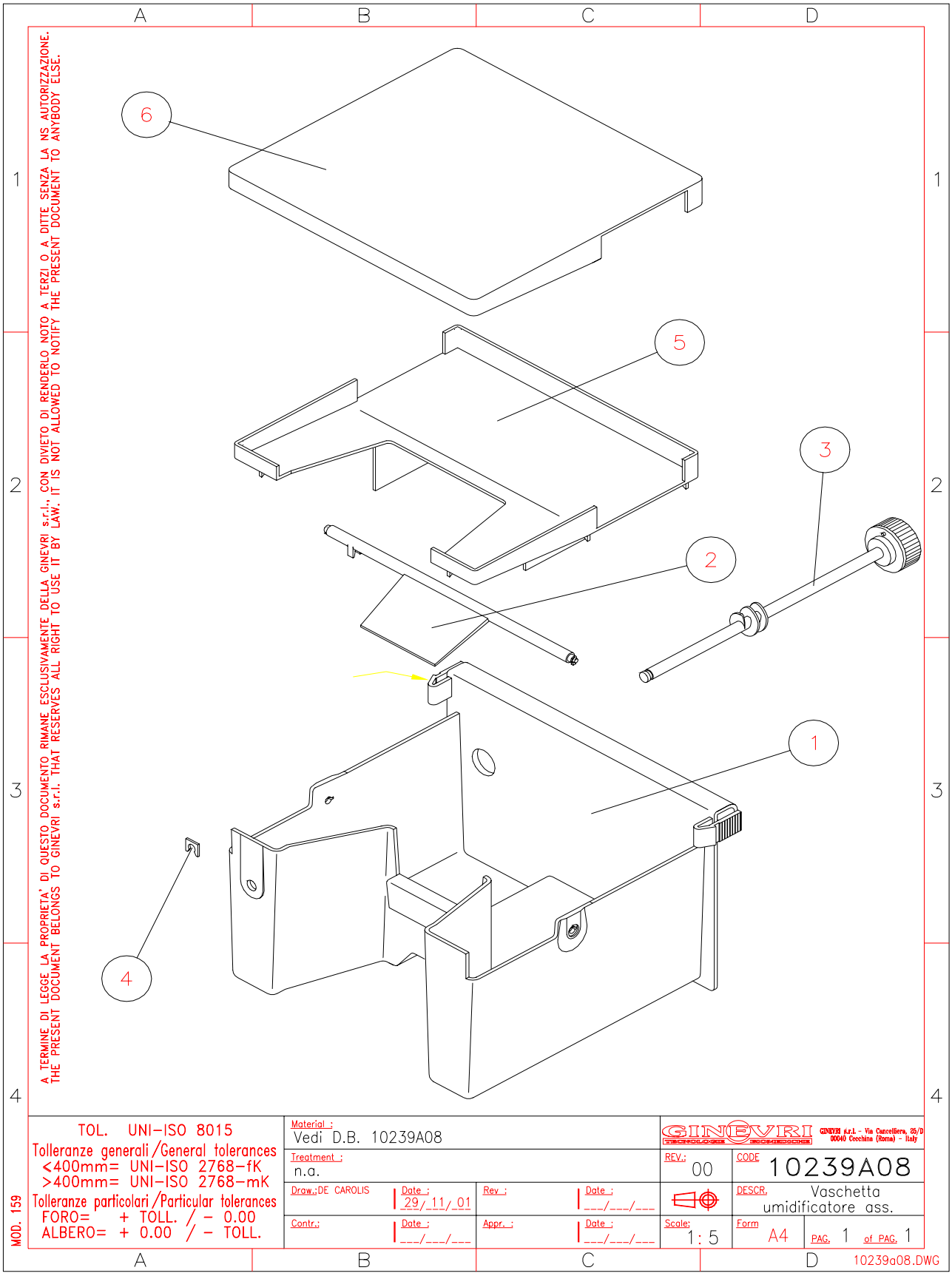
Item	*Code*	*Description*		*Q.ty*
8	11233A72	ASSEMBLED ENGINE GROUP	NR	1,0000
16	11134B72	SECURITY THERMOSTAT	NR	1,0000
9	4906A72	FAN	NR	1,0000
1	5848A72	INTERNAL BODY CONTROL PANEL	NR	1,0000
7	6912A72	FAN FAILURE SENSOR	NR	1,0000
10	11882A72	RESISTANCE 280W 220V X OGB POLY	NR	1,0000

5.3 ASSEMBLED BODY INCUBATOR



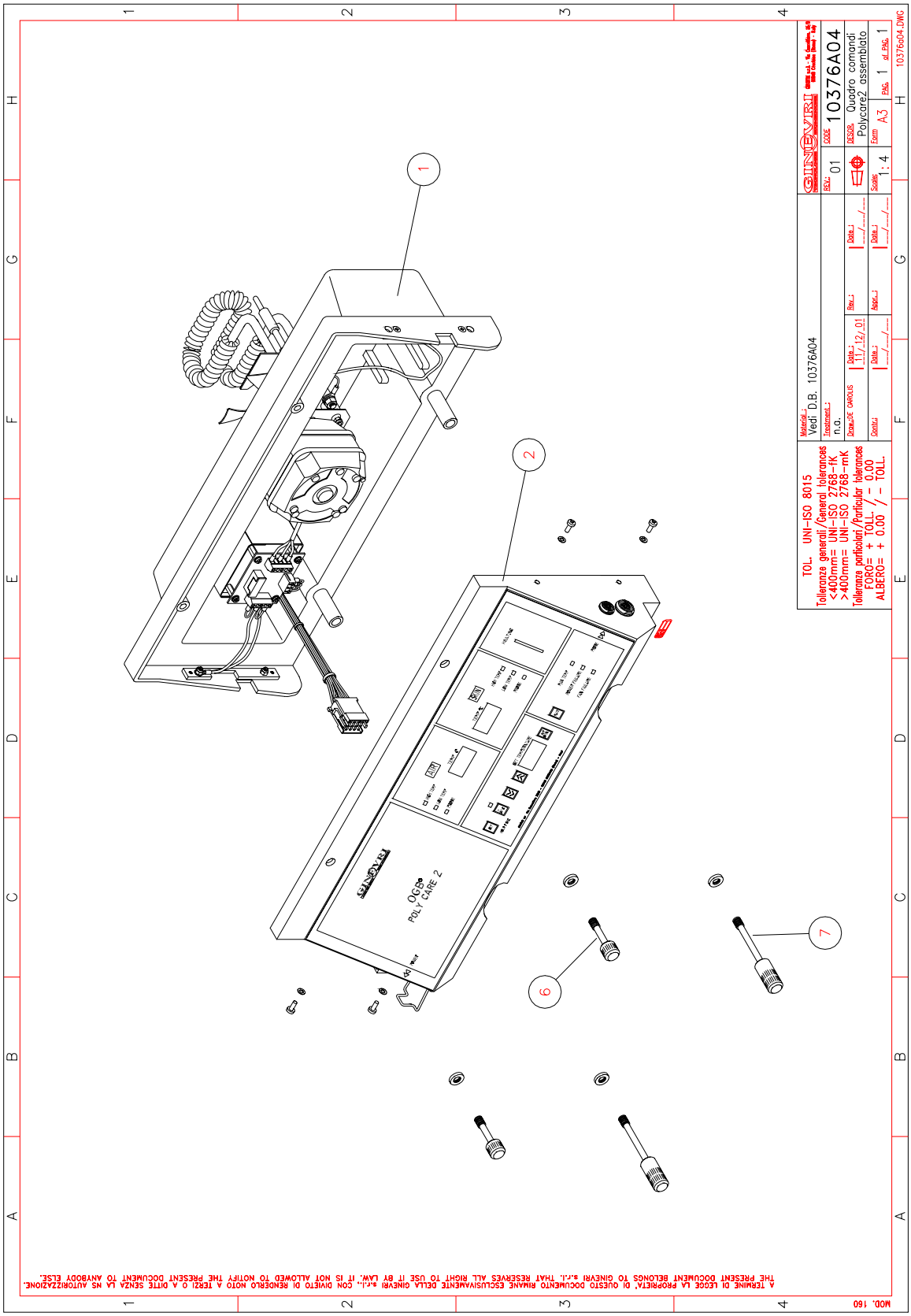
Item	*Code*	*Description*	*Q.ty*	
1	**10106A72**	COMPLETED BASAMENT	NR	1,0000
2	11315A72	MICROFILTER COVER	NR	1,0000
5	6100A72	PATIENT TRAY	NR	1,0000
4	7320A72	AIR CONVEYOR	NR	1,0000
7	11835A72	ASSEMBLED HOOD	NR	1,0000

5.4 ASSEMBLED WATER BOX



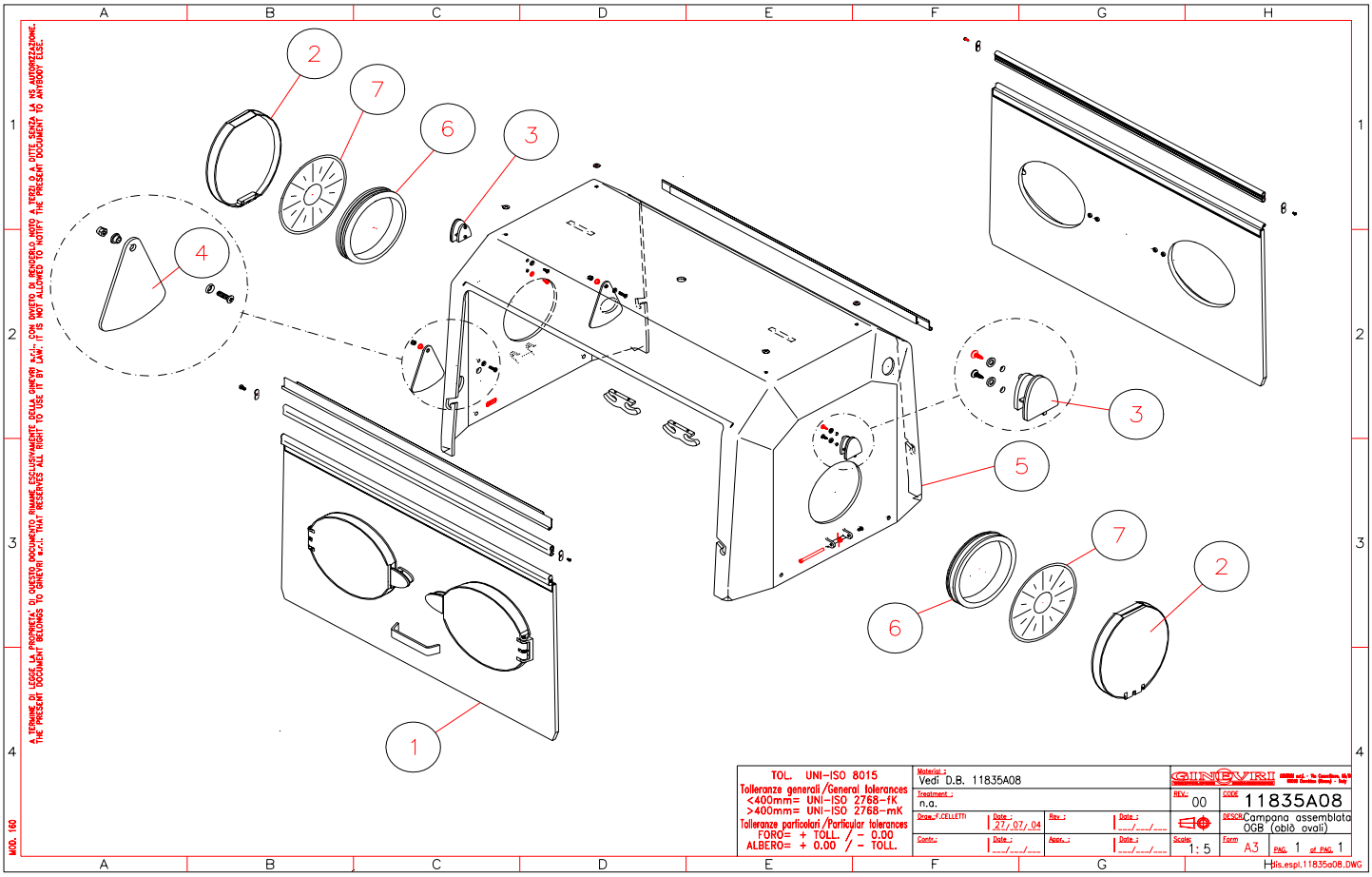
Item	*Code*	*Description*	*Q.tà*	
1	5847A72	WATER BOX	NR	1
5	5849A72	LOWER HALF-COVER	NR	1
6	5927A72	UPPER HALF-COVER.	NR	1
2	5928A72	POLE WITH DEFLECTOR	NR	1
3	5929A72	PIVOT PIN	NR	1
4	5930A72	LOCK FOR PIVOT PIN	NR	1

5.5 ASSEMBLED CONTROL PANEL



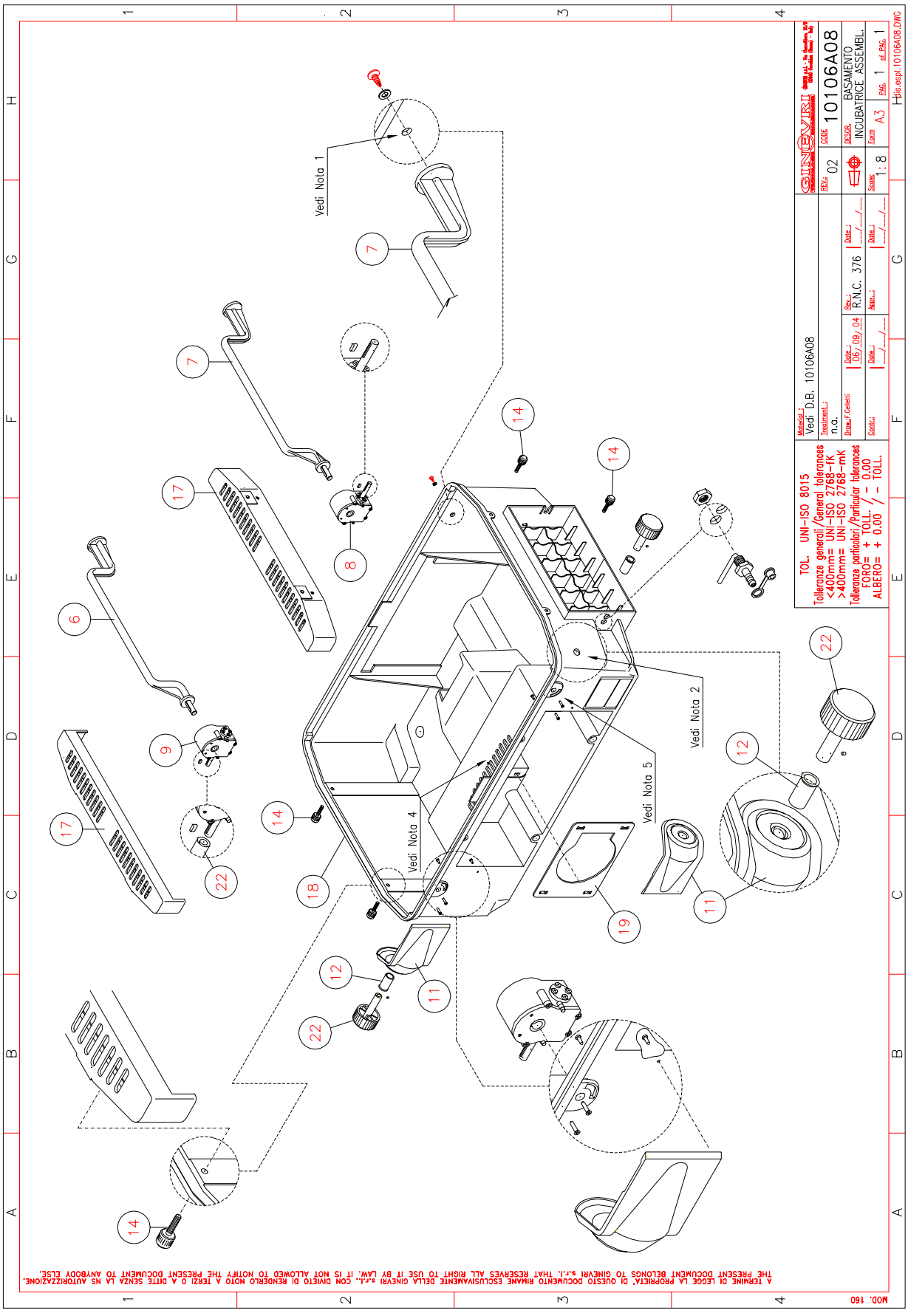
Item	*Code*	*Description*	*Q.ty*	
1	10181A06	POWER SUPPLY UNIT	NR	1,0000
7	10183A20	KNURLED KNOB M8X60	NR	2,0000
6	10185A20	KNURLED KNOB M8X30	NR	2,0000
2	10399A06	KEYBOARD UNIT	NR	1,0000

5.6 ASSEMBLED HOOD



Item	*Code*	*Description*	*Q.ty*
1	10231B72	HOOD DOOR PANEL OVAL PORT ASSEMBLY	1
2	11745A72	OGB INCUBATOR OVAL PORTHOLE	2
3	11750A72	PUSH OPENERS FOR ACCESS PORTS	6
4	2592A72	TRIANGLE FOR OGB	2
5	7460A72	OGB INCUBATOR HOOD LEXAN N/MOD	1
6	12029A73	RUBBER SEAL FOR THE HOOD (ROUND HOLES)	6
7	11725A73	SLEEVE FOR PORTHOLE	12

5.7 ASSEMBLED BASAMENT



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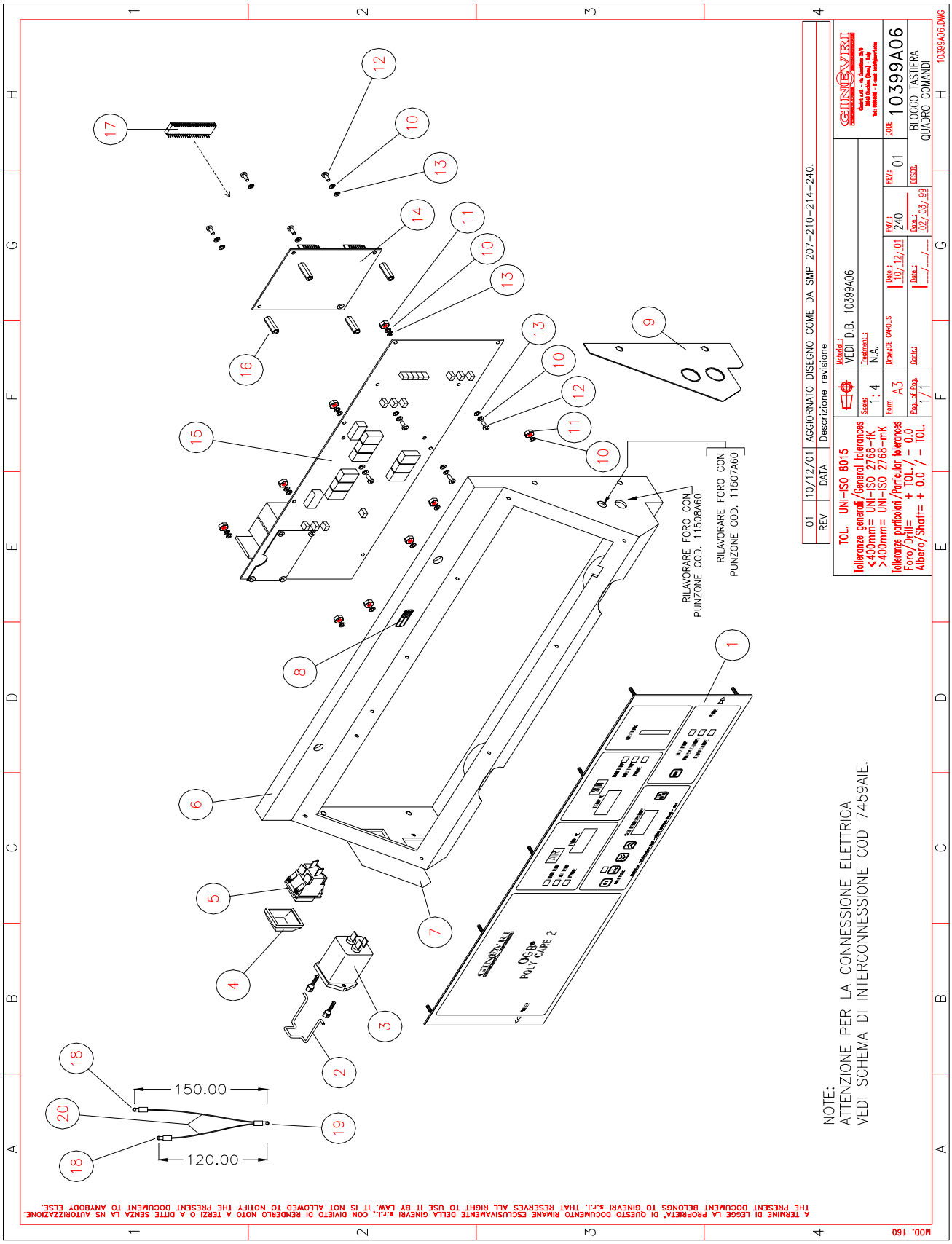
Item	*Code*	*Description*	*Q.ty*	
6	10107A72	TRAY POSITIONING LEVER LEFT	NR	1
7	10108A72	TRAY POSITIONING LEVER RIGHT	NR	1
8	10244A72	SMOOTH TILT LEFT	NR	1
9	10245A72	SMOOTH TILT RIGHT	NR	1
11	10744A72	SMOOTH-TILT KNOB CASE	NR	2
12	10745A72	SMOOTH TILT KNOB PASSING BEARING	NR	2
14	1660A72	KNOB M6X25	NR	4
17	453A72	HOLED LONGERON X OGB	NR	2
18	5846A72	BASE OGB LEXAN	NR	1
19	5932A72	ORIFICE PLATE OGB/2000 LEXAN	NR	1
22	7702A72	KNOB D50 X SHAFT D8	NR	2

5.8 CONTROL PANEL LOCKED KEYBOARD


RILAVORARE FORO CON PUNZONE COD. 1508A60
RILAVORARE FORO CON PUNZONE COD. 1507A60
150.00
120.00
NOTE:
ATTENZIONE PER LA CONNESSIONE ELETTRICA
VEDI SCHEMA DI INTERCONNESSIONE COD 7459AIE.
01 10/12/01 AGGIORNATO DISEGNO COME DA SMP 207-210-214-240.
REV DATA Descrizione revisione
TOL. UNI-ISO 8015
Tolleranze generali/General tolerances
<400mm= UNI-ISO 2768-fK
>400mm= UNI-ISO 2768-mK
Tolleranze particolari/Particular tolerances
Foro/Drill= + TOL./ - 0.0
Albero/Shaft= + 0.0 / - TOL.
Materiali: VEDI D.B. 10399A06
Scala: 1 : 4
Form: A3
Pag. of Pag.: 1/1
Trattamenti: N.A.
Disegnato: CAROLUS
Controllato:
Data: 10/12/01
Data: 02/03/99
Rev.: 240
REV.: 01
DESIGN: BLOCCO TASTIERA QUADRO COMANDI
CODE: 10399A06
GINEVRI
10399A06.DWG
MOD. 160
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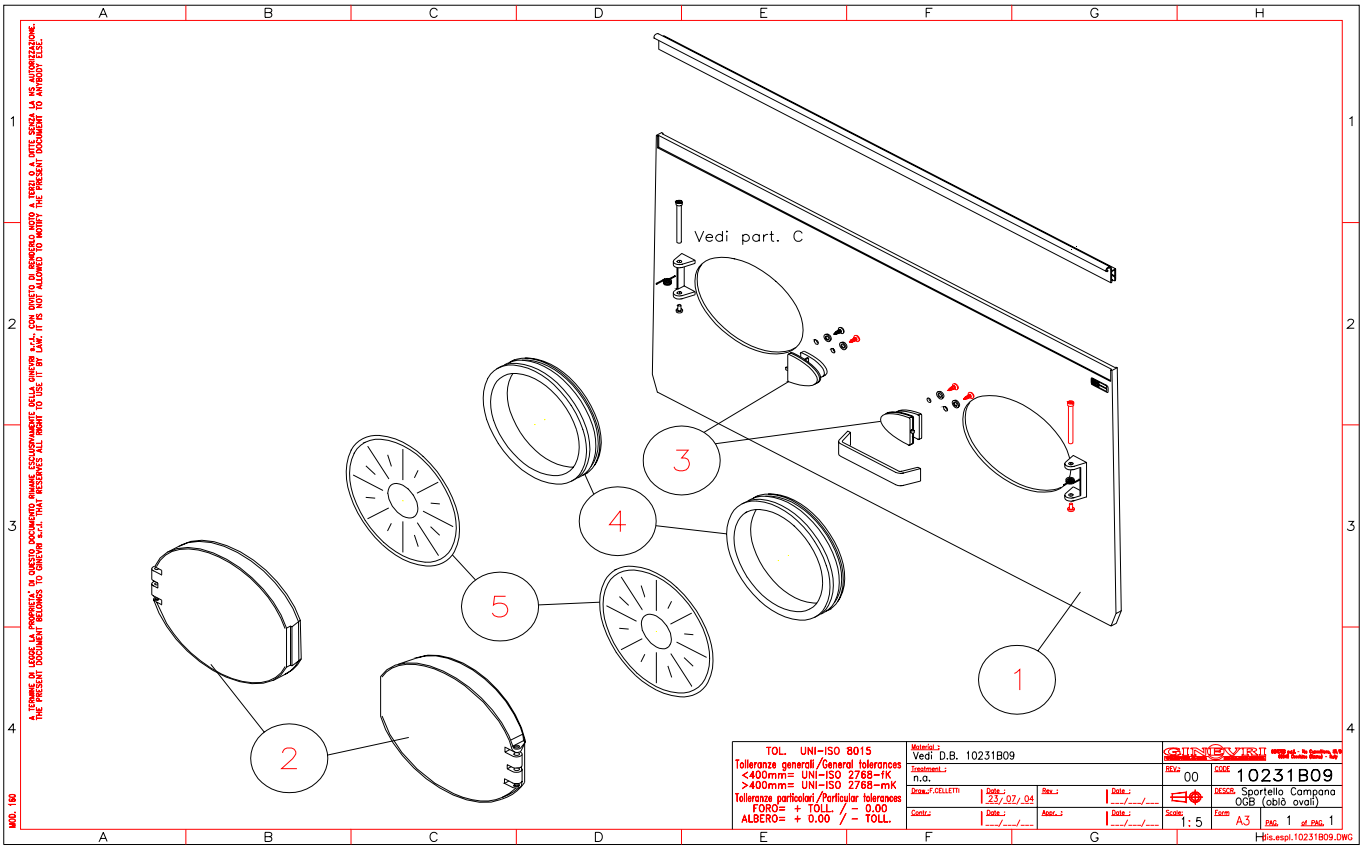
Item	*Code*	*Description*	*Q.ty*	
3	11767A72	SOCKET IEC W/FILTER AND FUSE	NR	1,0000
17	10404A72	EPROM	NR	1,0000
4	10531A72	SWITCH PROTECTION 30X24	NR	1,0000
7	10932A72	LEFT LABEL SIDE	NR	1,0000
9	10934A72	RIGHT LABEL SIDE	NR	1,0000
14	11218A72	MICROPROCESSOR BOARD	NR	1,0000
6	122A72	FRONT CARTER	NR	1,0000
5	6422A72	GREEN SWITCH ON/OFF	NR	1,0000
1	7419A72	KEYBOARD	NR	1,0000
15	7434A72	CONTROL BOARDS	NR	1,0000

5.9 ASSEMBLED WOOD DOOR



Rif.	Code	*Description*	*Q.ty*
1	11744A72	OGB INCUB.DOOR WITH OVAL PORTS	1
2	11745A72	OVAL ACCESS PORTS OGB INCUB.	2
3	11750A72	PUSH OPENERS FOR ACCESS PORTS	6
4	11721A73	RUBBER SEAL FOR DOORS WITH OVAL PORTHOLES	6
5	11725A73	SLEEVE FOR PORTHOLE	12

6. MAINTENANCE SERVICE

Ginevri representative in your country can stipulate, within one month before warranty period expiry, various kinds of maintenance contract.

For any inquiry please contact us:

Ginevri s.r.l.
Via Cancelliera, 25/B
00041 Cecchina (Roma)
Italy
Tel. +39 06 93459331
Fax. +39 06 93459393
email. export@ginevri.com

The device is manufactured in compliance with the standards CEI 62.5 (file 1445 of 01/91) and EN 60 601-1 and related IEC 601-2-50. Moreover the device is provided with an EMC (electromagnetic compatibility) anti-jamming device.

If servicing/maintenance after warranty period is performed by other companies not qualified/authorized by us, all fixed parts have to be marked by the repairer. The repairer has to verify and guarantee in writing the perfect functioning of the device. Any modification of the device must comply with the Medical Devices Normative law 93/42/CEE and approved by Ginevri s.r.l.

For maintenance service original materials must be used.

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7. PROGRAMMED AND PREVENTIVE MAINTENANCE

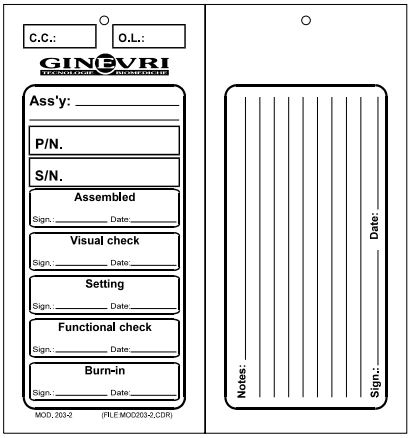
All electromedical devices must be maintained regularly, as for the normative law (CEI 1276 G).
The aim of preventive and programmed maintenance is to minimise the need of faults repairing and to obtain:

- **Correct functioning;**
- **Safety for the patient, the operator and the surrounding environment;**
- **Maximum availability of the device.**

Preventive maintenance consists in controls performed by the operator and periodical maintenance. Written programs should be defined regarding every kind of device, based on laws, technical standards and suggestions of the manufacturer. These programs must include controls performed by the operators and periodical maintenance.

8. FINAL CHECK

If all test operations are successfully completed, sign and stamp the Functional-Check field and tick the Setting field of the label attached to the device, as shown in the following picture.



If test operations are not successfully completed, state whether the OGB Polycare Infant Incubator has to be repaired or replaced. In case it has to be repaired, this can be done immediately (urgent cases) or afterwards. If the maintenance can be performed afterwards, place a red mark on the device and leave it in the area dedicated to materials waiting for maintenance for a further service. Write down the anomalies in the Notes field on the back of the label.
If the OGB Polycare Infant Incubator has to be replaced, fill in the non-conformity statement, according to PO-10.

9. TECHNICAL DATA

FRAME	***POLYCARBONATE***
POWER SUPPLY	***220V 50/60 HZ***
POWER DRAIN	***330W (540W HOT SPOT)***
SAFETY CLASS	***I***
CATEGORY	***B***
GROUND DISPERSION CURRENT	***50 µ A***
ELECTRICAL PROTECTION	***2 FUSES 5X20MM 2 AMP F***
POWER FAILURE ALARM BATTERY	***INCLUDED***
SKIN TEMPERATURE DISPLAY	***0.1°C RESOLUTION, 0.3°C MAX ERROR***
AIR TEMPERATURE DISPLAY	***0.1°C RESOLUTION, 0.6°C MAX ERROR***
HIGH TEMPERATURE ALARM	***(only Automatic mode) ACOUSTIC/VISUAL AUTOMATIC (+1°C with respect to SET TEMP)***
ENVIRONMENT OPTIMUM TEMPERATURE	***21°C /26°C***
STORAGE TEMPERATURE	***-10°C/+50°C***
MAXIMUM WHEIGHT ON PATIENT BED	***10 KG***
MAXIMUM DIMENSIONS	***83x59x68 cm***
WHEIGHT	***51 kg***

10. OGB POLY CARE 2 COMPLIES WITH THE FOLLOWING STANDARDS:

IEC	**601.1**	**(CEI 62.5)**
IEC	**601.2.19**	
EN	**55011**	
EN	**61000-4-2**	
EN	**61000-4-3**	
EN	**61000-4-4**	
EN	**61000-4-5**	
EN	**61000-4-11**	

MEDICAL DEVICE 93/42/CEE
CLASS II b

SINCERT IMQ

UNI EN ISO 9000:2000 – CERTIFIED QUALITY SYSTEM BY IQNET – No. CERT –IT-37100
UNI CEI ISO 13485 – PARTICULAR REQUIREMENTS FOR MEDICAL DEVICES

CE 0051